

## II. REMARKS

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow. Claims 1, 2, and 4-30 are pending in the application. Claims 2, 4-11 and 14-30 have been withdrawn from further consideration pursuant to 37 CFR 1.142(b).

This Reply changes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented above, with an appropriate defined status identifier.

After amending the claims as set forth above, claims 1, 12 and 31 to 33 are pending in this application. Claim 1 has been amended to indicate that the lung cancer sample has been isolated from a patient and that the method is to determining neoplastic potential of a lung cell. Support for this amendment and the addition of new claims 31 to 33 is found in the substitute specification on page 4, lines 21 to 26; page 35, line 19 to page 36, line 19 to page 39, line 10 and page 40, lines 1 to 24. Accordingly, and issue of new matter is not raised by these amendments and entry thereof is respectfully requested.

### 35 U.S.C. § 102

The Examiner maintained the rejection of claims 1, 12, and 13 under 35 U.S.C. § 102 (b) as allegedly anticipated by Mooi et al. (Histopathology (1988) 3:329-337), as evidenced by Wilkinson et al. (Science (1989) 246(4930): 670-673).

The Office noted Applicants' prior remarks made to distinguish the claimed invention from the teachings of the cited references, namely that Mooi et al. does not anticipate each and every limitation of the claims, since, in particular, Mooi et al. does not explicitly teach the proto-oncogene encoding PGP9.5 is "over-expressed" in lung cancer or that its over-expression is indicative of a neoplastic condition of lung cells.

Claim 1 and therefore dependent claim 12 have been amended herein to more clearly point out and distinctly claim an aspect of this invention, i.e., that the proto-oncogene

PGP9.5 is a tumor marker that is useful to correlate the neoplastic potential of a lung cell. Mooi et al. cannot teach or suggest this method because all samples tested by Mooi et al. were cancer cells and therefore were by their very nature neoplastic. Wilkinson et al. does not add to the teachings of Mooi et al. since Wilkinson et al. did not screen normal or lung cancer cells. Wilkinson et al. does state, as the Office indicated, that expression of the PGP9.5 marker is tissue specific, but it does not teach that it is not found on normal lung cells as the Office asserts. The statement in the reference that the marker is tissue specific appears to summarize the finding that it was specific within neuroendocrine tissues (see page 671, first full paragraph of extreme right hand column of the page). Thus, Mooi et al. as evidenced by Wilkinson et al. does not anticipate the claimed invention and the rejection of all claims now pending under 35 U.S.C. § 102 should be removed.

New claim 31 further describes the neoplastic potential as being to develop into a non-small cell lung cancer cells. This claim, supported on page 3, lines 17 and 18 of the substitute specification, is not anticipated for the reasons provided for claims 1 and 12, above.

New claim 32 further notes that the neoplastic potential is independent of any neuroendocrine features of the cell. New claim 32 is supported on page 4, lines 22 to 25 of the substitute specification. Mooi et al. (even as evidenced by Wilkinson et al.) did not address this issue since the authors were only investigating whether or not the marker was a neuronal differentiation marker. Not all lung tumors are of neuroendocrine origin. Thus, Mooi et al. does not anticipate new claim 32.

New claim 33 further defines the neoplastic potential as comprising metastatic potential. New claim 33 is supported on page 39, lines 8 to 10 of the substitute specification. Mooi et al. (even as evidenced by Wilkinson et al.) did not address this issue since the authors were only investigating whether or not the marker was a neuronal differentiation marker. Mooi et al. does not anticipate new claim 33.

#### **Oath or Declaration**

Applicants' acknowledge the Office's request for a substitute oath or declaration.

### III. CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is fully in condition for allowance, and such action is earnestly solicited.

If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

The undersigned has made a good faith effort to respond to all of the rejections in the case and to place the claims in condition for immediate allowance. Nevertheless, if any undeveloped issues remain or if any issues require clarification, the Examiner is respectfully invited to call the undersigned in order to resolve such issue promptly.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872.

Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

By 

Date: April 13, 2006

FOLEY & LARDNER LLP  
Customer No. 37806  
Telephone: (650) 251-1129  
Facsimile: (650) 856-3710

Antoinette F. Konski  
Attorney for Applicant  
Registration No. 34,202